UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,935	12/22/1998	JACQUES DUMAS	BAYER 12P1	7400

7590 05/27/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
05/27/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JACQUES DUMAS

Appeal 2008-0586
Application 09/776,935
Technology Center 1600

Decided: May 27, 2008

Before RICHARD E. SCHAFER, RICHARD TORCZON, and JAMES T. MOORE, *Administrative Patent Judges*.

MOORE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

The Appellant appeals under 35 U.S.C. § 134 (2002) from a final rejection of claims 17-24, 26, and 30-32.[1] We have jurisdiction under 35 U.S.C. § 6(b) (2002).

The Appellant's claims are directed to methods of treating rheumatoid arthritis, Crohn's disease and related inflammatory conditions through inhibition of p38 kinase activity using aryl and heteroaryl substituted heterocylic ureas.

[1] Claims 1-16, 25 and 27-29 have been canceled.

Claims 17 and 30 are the only independent claims in the application. The Appellant does not argue any claims or rejections separately. Therefore, we select independent claim 17 upon which to decide the appeal. See 37 C.F.R. § 41.37(c)(1)(vii)(2006). Accordingly, the remaining claims stand or fall with claim 17.

Claim 17 reads as follows:

> 17. A method for the treatment of rheumatoid arthritis which comprises administering to a patient in need thereof an effective amount of a compound of formula I or a pharmaceutically acceptable salt thereof
>
> 
>
> I
>
> wherein B is phenyl, pyridinyl, pyrimidinyl, pyrazinyl, pyridazinyl, naphthyl, quinolinyl, isoquinolinyl, phthalimidinyl, furyl, thienyl, pyrrolyl, imidazolyl, pyrazolyl, oxazolyl, isoxazolyl, thiazolyl, isothiazolyl, benzofuryl, benzothienyl, indolyl, benzopyrazolyl, benzoxazolyl, benzisoxazolyl, benzothiazolyl or benzisothiazolyl substituted by –Y-Ar; and is optionally substituted by one or more substituents independently selected form the group consisting of halogen, up to per-halosubstitution, and X_n,
>
> wherein n is 0-3 and each X is independently selected from the group consisting of – CN, $-CO_2R^5$, $-C(O)NR^5R^{5'}$, $-C(O)R^5$, $-NO_2$, $-OR^5$, $-SR^5$, $-NR^5R^{5'}$, $-NR^5C(O)OR^{5'}$, $-NR^5C(O)R^{5'}$, C_1-C_{10} alkyl, C_2-C_{10} alkenyl, C_1-C_{10} alkoxy, C_3-C_{10} cycloalkyl, phenyl, pyridinyl, naphthyl, isoquinolinyl, quinolinyl, up to per halo-substituted C_1-C_{10} alkyl, up to per halosubstituted C_2-C_{10} alkenyl, up to per halo-substituted C_1-C_{10} alkoxy, up to per halo-substituted C_3-C_{10} cycloalkyl, and
>
> wherein R^5 and $R^{5'}$ are independently selected from H, C_1-C_{10} alkyl, C_2-C_{10} alkenyl, C_3-C_{10} cycloalkyl, up to per-halosubstituted C_2-C_{10} alkenyl and up to per-halosubstituted C_3-C_{10} cycloalkyl,
>
> wherein Y is - O-, -S-, $-N(R^5)-$, $-(CH_2)_m-$, -C(O)-, -CH(OH)-, $-(CH_2)_mO-$, $-NR^5C(O)NR^5NR^5-$, $-NR^5C(O)-$, $-C(O)NR^5-$, $-(CH_2)_mS-$, $-(CH_2)_m-N(R^5)-$, $-O(CH_2)_m-$, $-CHX^a-$, $-CX^a{}_2-$, -S-$(CH_2)_m-$

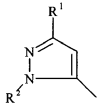
and -N(R^5)$(CH_2)_m$-,

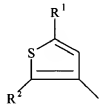
m= 1-3, and X^a is halogen; and

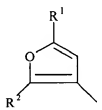
Ar is phenyl, pyridinyl, pyrimidinyl, pyrazinyl, pyridazinyl, naphthyl, quinolinyl, isoquinolinyl, phthalimidinyl, furyl, thienyl, pyrrolyl, imidazolyl, pyrazolyl, oxazolyl, isoxazolyl, thiazolyl, isothiazolyl, benzofuryl, benzothienyl, indolyl, benzopyrazolyl, benzoxazolyl, benzisoxazolyl, benzothiazolyl or benzothiazolyl, optionally substituted by halogen up to per-halosubstitution and optionally substituted by Z_{n1}, where n1is 0 to 3 and

each Z is independently selection from the group consisting of CN, =O, -CO_2R^5, -C(O)$NR^5R^{5'}$, -C(O)- NR^5, -NO_2, -OR^5, - SR^5, -$NR^5R^{5'}$, -$NR^5C(O)OR^{5'}$, -C(O)R^5, -$NR^5C(O)R^{5'}$, -SO_2R^5, $SO_2NR^5R^{5'}$, C_1-C_{10} alkyl, C_1-C_{10} alkoxy, C_3-C_{10} cycloalkyl, up to per halo-substituted C_1-C_{10} alkyl, and up to per halo-substituted C_3-C_{10} cycloalkyl, and

wherein A is a heteroaryl selected from the group consisting of



,


and


wherein R^1 is selected from the group consisting of C_3-C_{10} alkyl, C_3-C_{10} cycloalkyl, up to per-halosubstituted C_1-C_{10} alkyl and up to per halo-substituted C_3-C_{10} cycloalkyl,

wherein R^2 is C_6-C_{14} aryl, or substituted C_6-C_{14} aryl,

wherein if R^2 is a substituted group, it is substituted by one or more substituents independently selected from the group consisting of halogen, up to per-halosubstitution, and V_n,

wherein n = 0-3 and each V is independently selected form the group consisting of -CN, -CO_2R^5, -C(O)$NR^5R^{5'}$, -OR^5, - SR^5, -$NR^5R^{5'}$, -C(O)R^5, -OC(O)$NR^5R^{5'}$, -$NR^5C(O)OR^{5'}$, -SO_2R^5, SOR^5, $NR^5C(O)R^{5'}$, -NO_2, C_1-C_{10} alkyl, C_3-C_{10} cycloalkyl, C_6-C_{14} aryl, C_3-C_{13} heteroaryl, C_7-C_{24} alkaryl, C_4-C_{24} alkheteroaryl, substituted C_1-C_{10} alkyl, substituted C_3-C_{10} cycloalkyl, substituted C_6-C_{14} aryl,

substituted C_3-C_{13} heteroaryl, substituted C_7-C_{24} alkaryl and substituted C_4-C_{24} alkheteroaryl,

where V is a substituted group, it is substituted by one or more substituents independently selected from the group consisting of halogen, up to per halo-substitution, -CN, $-CO_2R^5$, $-C(O)R^5$, $-C(O)NR^5R^{5'}$, $-NR^5R^{5'}$, $-OR^5$, $-SR^5$, $-NR^5C(O)R^{5'}$, $-NR^5C(O)OR^{5'}$, and $-NO_2$,

wherein R^5 and R^6 are each independently as defined above.

THE REJECTIONS

The following rejections are before us for review:

1. Claims 17-19, 22, 26, and 30-32 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

2. Claims 17-24, 26 and 30-32 stand provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/947,761.

We AFFIRM in part and REVERSE in part.

ISSUE

Has the Appellant established that the Examiner erred in determining that the specification does not provide sufficient guidelines to enable of one of ordinary skill in the art to practice the claimed invention without undue experimentation?

Has the Appellant established that the Examiner erred in determining that the claimed invention is not patentably distinct from the reference?

PRINCIPLES OF LAW

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application…." *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

"That some experimentation is necessary does not constitute a lack of enablement; the amount of experimentation, however, must not be unduly extensive." *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1212 (Fed Cir. 1991). Factors considered in determining whether undue experimentation would have been required to practice the claimed invention include "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

ANALYSIS

I. The Rejection of Claims 17-19, 22, 26, and 30-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claims 17-19, 22, 26, and 30-32 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. (Non-Final Rejection, Jul. 3, 2006, p. 5). Specifically, the Examiner found

that the specification fails to provide information sufficient to allow a skilled artisan to practice the invention without undue experimentation. (Id.). The representative claim, independent claim 17, recites, in part, "A method for the treatment of rheumatoid arthritis which comprises administering to a patient in need thereof an effective amount of a compound of formula I or a pharmaceutically acceptable salt thereof…." (App. Br. 9-10)(emphasis added).

The specification describes that compounds of formula I are useful in the treatment of rheumatoid arthritis because the compounds have been found to inhibit p38, a protein kinase, which inhibition is known in the art to inhibit cytokine production, e.g., TNFα, and proteolytic enzyme production, e.g., MMP-1 and MMP-3. (Specification 2-5). The specification states that "[c]linical studies have *linked* TNFα production and/or signaling to a number of diseases including rheumatoid arthritis." (Id. 2)(emphasis added). Additionally, the specification states that "excessive levels of TNFα have been implicated in a wide variety of inflammatory and/or immunomodulatory diseases." (Id.).

After referencing a list of partially cited journal articles, the specification concludes, "Because inhibition of p38 leads to the inhibition of TNFα production, p38 inhibitors will be useful in treatment of the above listed diseases." (Id. 2-5). The specification similarly concludes, "Because inhibition of p38 leads to the inhibition of MMP production, p38 inhibitors will be useful in treatment of the above listed diseases." (Id. 5). Thus, the Appellant asserts that the claimed invention treats rheumatoid arthritis by inhibiting p38, which leads to the inhibition of TNFα and MMP, which are

"effector molecules … critical for the progression of rheumatoid arthritis." (Id. 1-5).

Formula I, as claimed, provides for a substantially large number of potential combinations as the formula includes A and B groups, each of which separately provide for numerous substitutions by multiple substituents. (See Claim 17, App. Br. 9). Based upon an exemplary calculation by the Examiner, the variations provided by formula I allow more than 100 million possible combinations.[2]

As examples of these numerous possibilities, the specification lists 38 compounds synthesized according to the general methods provided. (Specification 40-44). Thirty-seven of the 38 compounds listed were categorized as "2-Substitued-5-*tert*-butylpyrazolyl Ureas." (Id. 40-43).

In a separate section of the specification, a p38 kinase assay is discussed. (Id. 44). This section states, "The in vitro inhibitory properties of *compounds* were determined using a p38 kinase inhibition assay." (Id.)(emphasis added). The assay detected p38 activity. (Id.). The specification does not state which "compounds" were subjected to the assay, nor does it describe the concentration of compound added to the reaction solution. The results of the assay were collectively reported with the single statement that "[a]ll *compounds exemplified* displayed p38 IC_{50}s of between 1nM and 10μM." (Id.).

However, individual results for the compounds analyzed were not provided. Nor did the specification provide any discussion or guidance

[2] The Appellant challenges this estimate, but does so without offering any supportive evidence. (Reply Br. 2). Nor does the Appellant venture an estimate of the vast number of potential compounds encompassed by the claim. (Id.).

regarding the significance of the assay results, e.g., an explanation or statement regarding the significance of the p38 IC_{50}s values observed in relation to p38 inhibition, i.e., an identification of which compounds exhibited significant p38 inhibitory activity. As the Examiner stated, while "the difference in activity of from 1nM to 10μM is more than 1000 fold," the specification provides no guidance as to which compounds demonstrated the greater and the lesser p38 inhibitory activity. (Answer 11-12). Nor is guidance provided as to whether an observable relationship exists between the compounds and their individual results, and, if so, what that relationship is.

The specification next describes that "*in vivo* inhibitory properties of selected compounds were determined using a murine LPS induced TNFα production *in vivo* model." (Id.). Again, the "selected compounds" for this test are not identified. Also unidentified are which "inhibitory properties" were determined. The specification does describe that "TNFα levels in sera were measured using a commercial murine TNF ELISA kit," (Id. 45), however, we are perplexed that data indicating the measured TNFα levels are not reported or otherwise discussed. Indeed, no results for this study are provided.

More problematic is the fact that the specification does not describe any experimentation for the subject of the claim, that is, the treatment of rheumatoid arthritis. As the Examiner stated, neither of the above-mentioned assays is specific for rheumatoid arthritis. (Answer 9, 12). Thus, the specification fails to describe how a skilled artisan can determine which, if any, of the numerous potential compounds encompassed by formula I actually function to treat rheumatoid arthritis.

While some guidance is provided to determine that the "compounds exemplified" inhibit p38 kinase, the specification fails to provide any meaningful direction or guidance for determining whether the observed inhibition of p38 kinase is sufficient to inhibit TNFα, and further, whether the observed p38 kinase inhibition is sufficient to inhibit TNFα in such a way as to effectively treat rheumatoid arthritis. The claimed effect of the formula I compounds on arthritic activity is not tested or otherwise supported in the specification. In other words, what qualifies as effective p38 inhibitory activity for the treatment of rheumatoid arthritis is neither addressed nor discussed in the specification. One of ordinary skill in the art is left not only to experiment on a vast number of compounds, but also is provided little guidance as to how to proceed.

Based on a careful consideration of the factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), the Examiner found that the specification fails to provide information sufficient to allow a skilled artisan to fully practice the invention without undue experimentation. (Non-Final Rejection, Jul. 3, 2006, p. 6).

The Appellant asserts that the Examiner's lack of enablement rejection is improper because "a person of ordinary skill in the art would not question the usefulness of a compound that inhibits p38 to treat rheumatoid arthritis." (App. Br. 2-4). Specifically, the Appellant asserts that "a nexus between the activity of the compounds and the claimed methods is more than adequately established in the specification and is more than adequately recognized by those of ordinary skill in the art."

In support, the Appellant recites the specification teaching that "inhibition of p38 has been shown to inhibit both cytokine production (e.g.,

TNFα, IL-1, IL-6, IL-8) and proteolytic enzyme production (e.g., MMP-1, MMP-3) in vitro and/or in vivo." (Id. 2-3)(quoting Specification 2:7-9). The Appellant also asserts that the specification provides citation to "a large volume of prior art that provides the nexus between, for example, TNFα and various diseases, including rheumatoid arthritis." (Id. 3). The Appellant additionally asserts that the specification describes that "[b]ecause inhibition of p38 leads to inhibition of TNFα production, p38 inhibitors will be useful in treatment of the above listed diseases." (Id. 3)(quoting Specification 5:1-2).

We are not persuaded of error on the part of the Examiner.

First, while the specification concludes that "[b]ecause inhibition of p38 leads to inhibition of TNFα production, p38 inhibitors will be useful in treatment of the above listed diseases," the Appellant has not persuasively established that this conclusory and absolute statement is supported by the evidence. (Specification 5:1-2).

As discussed, the specification does not provide any experimentation of any compounds in an accepted specific rheumatoid arthritis assay. Additionally, the specification does not provide an assertion that any of the referenced articles specifically describe that inhibition of TNFα, via inhibition of p38 kinase, leads to the *treatment* of rheumatoid arthritis. The specification merely asserts that "[c]linical studies have *linked* TNFα production and/or signaling to a number of diseases including rheumatoid arthritis." (Id. 2:11-13) (emphasis added). The specification describes this "link" is that "excessive levels of TNFα have been implicated in a wide variety of inflammatory and/or immunomodulatory diseases." (Id. 2:13-14).

As discussed, supra, what is missing from the specification and the referenced prior art is sufficient direction or guidance for determining which compounds of formula I that are found to inhibit p38 kinase activity do so in a manner sufficient to inhibit TNFα to a degree that causes a therapeutic effect in rheumatoid arthritis, as claimed. Without this guidance, undue experimentation of a skilled artisan would be required to make and use the invention of claim 17.

Moreover, the failure of the specification to provide such guidance is not overcome by the Appellant's assertion that there are "at least three FDA approved rheumatoid arthritis therapeutics whose target is TNFα…." (App. Br. 3). This is merely attorney 'testimony' and is not evidence sufficient to show that the missing guidance was available to one of ordinary skill in the art.

Similarly unpersuasive are the "various abstracts from PubMed" that the Appellant asserts were submitted during the prosecution of the application. (Id.). The Appellant asserts that these abstracts "provide insight into the treatment of rheumatoid arthritis and its relation, i.e., nexus, to p38." (Id.). The Appellant lists only one reference, "Badger, A.M. et al. (1996) Pharmacological profile of SB 203580, a selective inhibitor of cytokine suppressive binding protein/p38 kinase, in animal models of arthritis, bone resorption, endotoxin shock and immune function. J Pharmacol Exp Ther 279, 1453-1461," that "predates" the current application. (Id.). This reference addresses a single selective inhibitor of cytokine suppressive binding protein/p38 kinase, SB 203580, a pyridinyl imidazole compound.

The Appellant has not offered any persuasive evidence demonstrating that the teachings in this reference describing activity of a pyridinyl imidazole p38 kinase inhibitor are applicable to the aryl ureas of the claimed formula I. Further, the Appellant has not established that the abstract provides the missing guidance regarding how to determine which compounds of formula I that are found to inhibit p38 kinase activity do so in a manner sufficient to inhibit TNFα to a degree that results in the treatment of rheumatoid arthritis.

The remaining abstracts submitted were published after the application filing date, as the Appellant admits. The Appellant asserts only that these postdated abstracts indicate the "art-recognized relation of the inhibition of p38 and the treatment of rheumatoid arthritis." (App. Br. 3). However, the later-published articles provided by the Appellant do not establish that the Examiner erred in determining the state of the art at the time of the invention. (See *In re Glass*, 492 F.2d 1228 (CCPA 1974)(application disclosure must be complete and enabling as of its filing date). In any event, the Appellant has not established that these abstracts supply the experimental guidance missing from the specification.

The Appellant next asserts that "the Office Action admits that the specification provides a showing that specific compounds of the invention are effective at inhibiting p38," and that this admission sufficiently demonstrates that the compounds treat rheumatoid arthritis and thus satisfies the enablement requirement. (App. Br. 4).

This argument is also unpersuasive. The Examiner stated in the office action that the "Applicant discloses 38 different ureas as ureas useful in *inhibiting* p38. The specification does not teach that the scope of the

invention is limited to these ureas and the claims do not claim a method of inhibiting p38, however." (Non-Final Rejection, Jul. 3, 2006, p. 7)(emphasis in original).

This statement does not represent a finding that the specification demonstrates that invention compounds effectively inhibit p38 or that they treat rheumatoid arthritis. Rather, the term "inhibiting" is clearly emphasized in italics to indicate some ambiguity regarding the disclosure. As the Examiner has explained, it is unclear that the 38 compounds listed in the specification are the same compounds subjected to the p38 kinase assay. (Answer 10). Further unclear is the significance of the reported p38 IC_{50}s values with respect to inhibitory activity.

Moreover, the Examiner's statement does not equate the disclosure of ureas useful in inhibiting p38 to usefulness in the treatment of rheumatoid arthritis. Instead, the Examiner makes the point that the activity of the compounds asserted by the Applicant's disclosure is not that which is claimed as the invention, i.e., a method for treating rheumatoid arthritis.

Next, the Appellant challenges that the Examiner's findings that the specification does not provide any indication that p38 invariably inhibits TNFα, that inhibition of p38 invariably treats rheumatoid arthritis, that any inhibition of TNFα treats rheumatoid arthritis, or that any of the claimed compounds are "actually effective" in treating rheumatoid arthritis are unsupported. (App. Br. 4)(citing Non-Final Rejection, Jul. 3, 2006, p. 7-8). Specifically, the Appellant asserts that it is not necessary for the claimed invention to provide 'invariable' treatment to satisfy the requirement of 35 U.S.C. § 112, first and second paragraph." (Id. 4-5). The Appellant further asserts, "A claim may encompass inoperable subject matter…."

(Id.). The Appellant also asserts that the "laboratory data provided is more than adequate to satisfy the statute." (Id. 5)(citing *Cross v. Iizuka*, 224 USPQ 739 (Fed. Cir. 1985)("in vitro results with respect to the particular pharmacological activity are generally predictive of in vivo test results").

This argument is also unpersuasive. While a claim may encompass *some* inoperable subject matter, it must encompass some operable matter. As the Federal Circuit has explained, "if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid." (*Atlas Powder Co. v. E.I. du Pont de Nemours*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984)).

Here, as explained, the specification does not provide persuasive evidence that even a single compound encompassed by formula I is operative in treating rheumatoid arthritis. Additionally, the laboratory data provided does not satisfy the enablement requirement, as discussed, supra. Indeed, the specification does not provided any laboratory data indicating that the assayed compounds treat rheumatoid arthritis. Consequently, we do not find that the Appellant has persuasively established the Examiner's challenged findings are erroneous.

The Appellant next challenges the Examiner's finding that the results of the p38 kinase assay of the "compounds exemplified" are unclear because the specification does not identify to which compounds the assay refers. (Id. 5; Reply Br. 1-2). In support of this challenge the Appellant asserts, "Table 1 lists all the exemplified compounds. Thus, there is no lack of clarity issue." (App. Br. 5).

We are not persuaded. Again, this is mere attorney argument which is not a substitute for evidence. Further, even when we look at it substantively, Table 1 appears in a separate section of the specification than the section describing the assays. In fact, the section in which the tables appear is titled "Examples," (Specification 27), and the tables are described only as listing compounds that "have been synthesized according to the General Methods listed above." (Id. 40). The next section, in which the assays are described, is separately titled "Biological Examples." (Id. 44).

As the Examiner stated, the assay section only generically refers to "compound," "compounds exemplified," and "selected compounds" as descriptions of the compounds subjected to the assays. (Id.). Therefore, we see no error with the Examiner's finding that the specification is ambiguous as to which compounds were assayed and the Appellant has not persuasively established otherwise.

Additionally, the Appellant challenges the Examiner's finding that the reported results are not adequate for understanding the scope and breadth of the invention because the activity profiles of the tested compounds are not taught. (Br. 5). The Appellant asserts that "[t]he scope of the claimed invention is clearly recited in the claims," and that that the activity profiles of the tested compounds are not required. (Id. 5-6)(citing *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971)("How [an objective enablement] teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.")).

This argument is also not persuasive. Claim 17 recites a formula I that encompasses a vast number of potential combinations that satisfy the formula. However, the subject of the claim is the treatment of rheumatoid

arthritis. There is no indication in the claim or the specification as to which structures satisfying formula I are effective in the treatment of rheumatoid arthritis. While the specification may rely upon examples or broad terminology to provide an enabling description of invention, as discussed, the Appellant has provided neither. Consequently, we do not find error with the challenged Examiner finding.

Finally, the Appellant challenges the Examiner's finding that "one of ordinary skill in the art would be forced to perform an exhaustive search for the embodiments … suitable to practice the claimed invention." (Id. 6)(quoting Non-Final Rejection, Jul. 3, 2006, p. 9). The Appellant asserts that in the field of pharmaceuticals, determining the activity of compounds is not undue experimentation, but "an industry wide acceptable routine amount of testing." (App. Br. 6). The Appellant also asserts that the specification provides "specific guidance as to how the claimed compounds can be tested for activity levels and actually provide data for specific compounds." (Id. 7). The Appellant further asserts that a skilled artisan would understand "how to proceed" in view of the prior art and the disclosure. (Id.).

This argument is also unpersuasive. We agree that the vast number of compounds, standing alone, may not render the experimentation undue. However, for the reasons previously stated, we do not find that the specification provides any meaningful guidance as to how to determine which of the vast number of claimed compounds are actually effective in treating rheumatoid arthritis.

Some incomplete guidance is provided to determine the p38 inhibition activity of some of the compounds, however the specification did not

provide "data for specific compounds," as the Appellant suggests. Rather, the results for all of the compounds subjected to the p38 kinase assay were reported collectively as falling within a broad spectrum of activity. The significance of the activity reported is not described. Nor does the specification even discuss whether the observed results indicate effective inhibition of p38 kinase, or define how effective inhibition would be observed. Additionally, the specification failed to provide any meaningful guidance as to how to determine whether the compounds found to exhibit effective p38 kinase inhibition did so in a manner sufficient to treat rheumatoid arthritis. As for the TNFα assay, the specification did not provide or discuss any results at all.

Consequently, the Appellant has not persuasively established that the experimentation required to make and use the claimed invention is either routine or is described by a reasonable amount of guidance with respect to the direction in which the experiment should proceed. (*See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)). The Examiner's finding that the specification fails to provide information sufficient to allow a skilled artisan to practice the invention without undue experimentation stands. Therefore, we do not find error with the Examiner's rejection that the claims contain subject matter that is not described in the specification so as to enable a skilled artisan to make and/or use the invention.

Accordingly, we affirm the Examiner's rejection.

II. The Provisional Rejection of Claims 17-24, 26, and 30-32 on the ground of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/947,761.

Claims 17-24, 26 and 30-32 stand provisionally rejected on the ground of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/947,761. The Examiner found that the conflicting claims, while not identical, are not patentably distinct from each other. (Non-Final Rejection, Jul. 3, 2006, p. 4).

Specifically, the Examiner found that claim 17 of the current application is drawn to a method for treating rheumatoid arthritis comprising administering a compound of formula 1 which is a urea with functionalities A and B. (Id. pp. 4-5). The Examiner also found that claim 1 of the '761 application is drawn to a method for treating diseases, other than cancer, mediated by p38, comprising administering a pharmaceutical composition comprising a compound of formula 1, which is also a urea with functionalities A and B. (Id. 5).

According to the Examiner, both the current claims and the '761 application claims define A and B as having an "equivalent scope and breadth." (Id.). The Examiner further found that claim 1 of the '761 application is broader than current claim 17. (Id.). Because the conflicting claims in the '761 application have not been patented, the Examiner designated this rejection as provisional. (Id.).

The Appellant challenges that the Examiner's rejection on the ground of obviousness-type double patenting is in error by pointing to two differences in the claims of the '761 application and claim 17, concluding that "the present claims differ from and do not overlap the A and B groups"

of the '761 claims, and thus one of ordinary skill in the art would not be "taught" to modify the A and B groups of the '761 claims to arrive at the instant claim. (App. Br. 7).

We initially note that the Appellant's assertion that the "B" group of the current claim is different from that of the '761 claims is simply incorrect. The -Y-Ar substituent pointed to by the Appellant as a difference is an optional selection for benzothiazolyl. Indeed, unsubstituted benzothiazolyl or other groups are also within the current claim's scope.

Nonetheless, we find that the Examiner has not provided a sufficient explanation or sufficient evidence to support the assertion that the A and B groups of the current claims and the '761 application claims have an "equivalent scope and breadth." (See Non-Final Rejection, Jul. 3, 2006, p. 5). Specifically, the Examiner has not established that the R^2 group in the instant claim has an equivalent scope as the R^2 group of the '761 claims.

We therefore agree with the Appellant that the Examiner has not established that the claims are patentably distinct. *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985).

Accordingly, we reverse this rejection.

CONCLUSION OF LAW

On the record before us, we conclude that the Appellants have not shown error on the part of the Examiner as to the enablement rejection. Specifically, the Appellant has not demonstrated error in the Examiner's finding that the specification does not provide sufficient guidelines to enable of one of ordinary skill in the art to practice the claimed invention without undue experimentation.

Additionally, we conclude that the Appellant has demonstrated error in that the Examiner has not established that claims 17-24, 26, and 30-32 are unpatentable on the ground of obviousness-type double patenting over claims 1-16 of copending Application No. 09/947,761.

DECISION

The Rejection of claims 17-19, 22, 26, and 30-32 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement is AFFIRMED.

The Rejection of claims 17-24, 26, and 30-32 on the ground of obviousness-type double patenting as being unpatentable over claims 1-16 of copending Application No. 09/947,761 is REVERSED.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED in part and REVERSED in part

Lb

Appeal 2008-0586
Application 09/776,935

cc (via U.S. Mail):

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
ARLINGTON COURTHOUSE PLAZA I
2200 CLARENDON BOULEVARD
SUITE 1400
ARLINGTON, VA 22201